UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,457	12/07/2001	Anthony Cerami	10162-006-999	5299

20583 7590 12/28/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,457	CERAMI ET AL.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *32-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, claims 1-31, in the reply filed on 29 September 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 32-52 have been withdrawn from consideration as being drawn to a non-elected invention. Upon further consideration, the species election has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, it is unclear whether the device is an immune modulation device because it is unclear whether the device can actually modulate an immune response without the antigen recited in claim 29. The preamble reciting use of the device in modulating an immune response lacks correlation with the claim, because it is unclear whether the device is capable of modulating an immune response as recited in claim 1.

Regarding claims 18-24, it is unclear whether the entire immune modulation device is intended to be made from the group of materials listed in claim 18, or whether the shell and fibrous scaffolding can be different materials.

Regarding claims 29-31, it is unclear whether the antigen may be anywhere on the device or whether the antigen must be contained in the interior lumen of the device. If the antigen is on the outside of the shell, it is unclear whether the device is capable of modulating an immune response.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 6-10, 15-21 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. (WO 99/44583) in view of Li et al. (US 6,303,136).

Cerami et al. teach an immune modulation device that is suitable for use in modulating an immune response in animals (pg. 1, lines 10-15), comprising: an impermeable biocompatible shell having an outer surface (impermeable, pg. 9, lines 4-7; hollow shell, pg. 14, lines 20-23) with a plurality of pores of suitable size to allow the ingress and egress of immune cells (pg. 10, lines 14-18) and the impermeable biocompatible shell having an interior lumen (interior lumen

contains porous matrix and antigen, pg. 9, lines 4-6 and 9-11), a porous sponge-like matrix being disposed within the interior lumen (pg. 9, lines 4-7). Cerami et al. fail to teach fibrous scaffolding being disposed within the interior lumen.

Li et al. teach a biocompatible fibrous scaffolding disposed within an interior lumen of a shell (col. 2, lines 31-37 and 44-56), in order to provide a linear environment to grow and proliferate within cell encapsulation devices.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the porous sponge-like matrix in the device of Cerami et al., fibrous scaffolding as taught by Li et al., in order to provide more even distribution to prevent cell clumping in the lumen and offer greater biological stability. Although the outer shell of Li et al. is used to encapsulate cells and the outer shell of Cerami et al. is used to promote ingress and egress of cells, the interior lumen are used for the same purpose of providing a scaffolding structure for attachment of cells. Therefore for reasons stated above, the interior scaffolding structure of Li et al. is more advantageous than that of Cerami et al., and the scaffolding of Li et al. can be substituted for the scaffolding Cerami et al.

Regarding claims 2, 3 and 6, Li et al. teach the fibrous scaffolding having a porosity between 20% to 95% (void volume, col. 4, lines 34-35), which encompasses the recited range of about 25% to about 95%. Li et al. also teaches the diameter of the filaments comprising the yarn is between 5-100 μm (col. 4, lines 39-40), which partially encompasses the recited range of less than 20 μm. Regarding claim 6, Li et al. teach a 44 denier multi filament yarn (col. 4, line 65), which is encompassed by the recited range of a bundle having a total denier of from about 20 to about 400 denier.

With respect to claims 7 and 8, Li et al. teach a fibrous scaffold of textured yarns (col. 4, lines 5-29), wherein the textured yarns of twisted and therefore torqued (col. 4, lines 30-39).

Regarding claims 9 and 10, Cerami et al. teach a tubing with a diameter, which indicates a cylindrical shape (pg. 14, lines 20-23; pg. 16, lines 10-18).

With respect to claims 15 and 16, Cerami et al. fail to teach the specific percentage or size of pores on the outer surface of the device. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 15 and 16 are for any particular purpose or solve any stated problem, and the prior art teaches that the number of pores and pore size can be adjusted in order to provide desired cellular ingress and egress and restrict and confine the diffusion of small molecules within the device, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the porous art.

Regarding claims 17-21, Cerami et al. teach the shell of the immune modulation device being made of polyglycolic acid (pg. 15, lines 19-24), which encompasses the recited glycolic acid and bioabsorable material.

With respect to claims 29-31, Cerami et al. teach the device comprising an antigen of an influenza virus (antigen in matrix, pg. 14, lines 16-19; influenza virus, pg. 19, lines 23-26).

4. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al., as applied to claim1, further in view of Roth et al. (US 4,128,612).

Cerami et al. in view of Li et al., as applied to claim 1, teach a device comprising a fibrous scaffolding structure in an interior lumen, but fail to specify the denier and diameter of the fibers.

Roth et al. teach that yarn into which polyglycolic acid is spun in the range of 2-6 denier (col. 5, lines 12-27), which partially encompasses the recited range of denier from about 0.8 to about 6 and about 0.2 to about 10, in order to provide convenient formation of fibers.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Cerami et al. in view of Li et al., fibrous filaments with a denier in the range of 2-6 as taught by Roth et al., in order to provide ease of spinning and sufficient flexibility of filaments.

5. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al, as applied to claim 10, further in view of Kennedy et al. (US 6,200,589).

Cerami et al. in view of Li et al., as applied to claim 10, teach a device having an outer diameter, but fail to teach an outer diameter of less than 1 mm.

Kennedy et al. teach a cylindrically shaped implantable medical device of less than 1mm (col. 5, lines 20-40), which encompasses the recited less than 750 microns, in order to provide a desired reservoir volume.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Cerami et al. in view of Li et al., a diameter of less than 1mm, in order to provide implantation with less invasive procedures.

Kennedy et al. also teach the thickness of the shell of the device between 0.001 and 0.1 cm (col. 5, lines 23-30), which encompasses the recited range of less than 250 microns and less than 150 microns.

6. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al., as applied to claim 20, and further in view of Bezwada et al. (US 5,597,579).

Cerami et al. in view of Li et al., as applied to claim 20, teach a device comprising an aliphatic of glycolic acid, but fail to teach a specific aliphatic polyester as specified in claim 22.

Bezwada et al. teach a polymer of p-dioxanone (col. 7, lines 10-16 and lines 26-49) or glycolide (col. 5, lines 5-12), in order to provide a polymer blend that can be injected into a mold to make an implantable medical device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the shell material of Cerami et al. in view of Li et al., a polymer of p-dioxanone, which is taught as functionally equivalent to glycolide and glycolic acid by Bezwada et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent aliphatic polymer materials and since only the expected material composition effect would have been obtained. The use of alternative and functionally equivalent materials would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Bezwada et al. also teach a fibrous scaffolding made from a polymer of p-dioxanone (col. 7, line 33-col. 21).

7. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al further in view of Bezwada et al., as applied to claim 24, and further in view of Dasch et al. (US 2003/0236192).

Cerami et al. in view of Li et al. and further in view of Bezwada et al., as applied to claim 24, teach a shell made from poly(p-dioxanone) and fibrous scaffolding made from a co-polymer of glycolide and lactide (Bezwada, col. 7, lines 99-16; col. 8, lines 19-20; col. 10, lines 38-50), but fail to teach specific weight percentages of glycolide and lactide.

Dasch et al. teach a scaffolding made from 90 weight percent glycolide and 10 weight percent lactide wherein the amount of lactide and glycolide can be adjusted to adjust polymer degradation rate (par. 56-57).

It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 25 are for any particular purpose or solve any stated problem, and the prior art teaches that the weights of polymers and amount of lactide to glycolide can be varied in order to obtain desired

physical properties such as mechanical strength, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the polymer forming art.

With respect to claim 26, Li et al. teach a fibrous scaffold of textured yarns (col. 4, lines 5-29).

8. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al. in view of Li et al further in view of Bezwada et al. ('579), as applied to claim 24, and further in view of Dasch et al. (US 2003/0236192) and Bezwada et al. (US 5,951,997).

Cerami et al. in view of Li et al. and further in view of Bezwada et al. and Dasche et al., teach a polymer blend which may comprise epsilon-caprolactone and glycolide (col. 7, lines 9-16) as a blend for implantable medical devices or sutures (col. 8, lines 51-56) and fibrous scaffolding made of glycolide and lactide, but fail to specifically teach glycolide and caprolactone in a polymer blend together.

Bezwada et al. ('997) teach glycolide and epsilon-caprolactone (col. 1, line 53-col. 2, line 9), in order to provide polymers with high tensile strength and knot fiber strength which are pliable. Although the polymer of Bezwada et al. provide for an additional monomer of p-dioxanone, the weight percentages of epsilon-caprolactone and glycolide recited in claim 27 can still be achieved through optimization.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Cerami et al. in view of Li et al. and further in view of Bezwada et al., a polymer of glycolide and epsilon-caprolactone as taught by Bezwada et al., in order to provide a desirable combination of tensile strength and flexibility. Furthermore,

since it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 27 are for any particular purpose or solve any stated problem, and the prior art teaches that the weights of polymers and amount of epsilon-caprolactone to glycolide can be varied in order to obtain desired physical properties such as mechanical strength, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the polymer forming art.

With respect to claim 28, Li et al. teach a fibrous scaffold of textured yarns (col. 4, lines 5-29).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re

Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-31 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,958,158 ('158). Although the conflicting claims are not identical, they are not patentably distinct from each other because: the subject matter claimed in the instant application obvious over the subject matter claimed in the patent, as follows: Regarding claims 1, 7 and 29 of the instant application, US patent '158 recites an immune modulation device that is suitable for use in modulation an immune response in animals, comprising: an impermeable biocompatible shell having an outer surface comprising a plurality of pores of suitable size, a biocompatible fibrous scaffolding being disposed within the interior lumen, the scaffolding comprising textured yarn and an antigen disposed within the interior lumen (claim 1). US patent '158 further recites the textured yarn containing crimped fibers having crimp points, which is not recited in the instant claims. However, such a limitation is not excluded by the instant claims, and therefore the claim of '158 is encompassed by the broader claims recited in the instant application. Regarding instant claims 2-6, '158 recites the recited porosity, scaffolding filament diameter, and the recited denier of filaments (claims 2-6). With respect to claim 7, patent '158 recites the specific textured yarn of bulked, coil, core and crinkle yarns (claim 7). With respect to instant claims 9-16, '158 recite a cylindrical shape of a three dimensional device, and specific diameters, wall thicknesses and porosity percentage and

size of the outer surface (claims 8-15). Regarding instant claims 17-28, '158 recites the specific materials recited in the instant application from which the device, shell, and scaffolding fibers are made (claims 16-25). Claims 26-27, '158 recites the specific antigens recited in instant claims 26 and 27 (claims 26-27).

Claims 1, 2, 7, 8, 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-12, 22 and 23 of copending Application No. 10/364,030 ('030). Although the conflicting claims are not identical, they are not patentably distinct from each other because: regarding instant claims 1, 2 16, '030 recites an implantable medical device comprising: a biocompatible shell comprising pores up to about 95% of the outer surface (claim 22), which encompasses about 25% to about 95% porosity, and a pore diameter of about 0.1 to about 500 microns, which encompasses about 10 to about 500 micron pore size (claim 23), and a biocompatible porous scaffold comprising a biocompatible fibrous, textured yarn (claims 2-4) disposed inside the interior lumen (claim 1). Regarding instant claims 17-21, '030 recites a bioabsorbable modulation device made from the materials specified in instant claims 18-21 (claims 8-12). Application '030 recites a mammalian cell type other than an immune cell seeded on a scaffold, which the instant claims fail to recite. The instant claims are written with open claim language "comprising" and therefore do not exclude the presence of a mammalian cell on a scaffold.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/12/05